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GENDER AND SURGICAL OUTCOMES AND MORTALITY AFTER PRIMARY TOTAL KNEE ARTHROPLASTY: A RISK-ADJUSTED ANALYSIS

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Abstract

Objective—Total knee arthroplasty (TKA) is a widely utilized and an effective treatment option for end-stage knee OA. Knee OA is more prevalent among women compared to men, but there are limited data on gender differences in surgical outcomes after total knee arthroplasty.

Methods—Our sample consisted of all primary TKA's performed in the State of Pennsylvania during the fiscal year 2002. We used ICD-9 codes to identify major complications and surgical revision. We used mixed effects logistic regression models to examine the associations between gender and all-cause mortality, readmissions, and major surgical complications. We used proportional hazards model to assess the risk of surgical revision after index arthroplasty. We adjusted for race, age, hospital teaching status, hospital procedure volume, insurance status and risk of mortality.

Results—In 17,994 primary TKA's, there were 46 deaths at 30-days and 220 at one-year. Compared to women, men had higher adjusted odds of one-year mortality (Odds Ratio (OR)=1.48; 95% CI=1.13–1.94) after primary TKA. The overall odds of most major 30-day complications did not differ by gender, except surgical wound infections, which were higher in men compared to women (OR= 1.31; 95% CI=1.08–1.60); 30-day readmission was higher in men (OR=1.25; 95% CI=1.10–1.43). Men had significantly higher rates of index knee arthroplasty revision at 5-years (hazard ratio= 1.20; 95% CI=1.05–1.36) compared to women.

Conclusion—Higher rates of mortality, hospital readmissions, revision surgery and wound infections in men undergoing elective TKA, compared to women, indicates gender disparity in these outcomes.

Introduction

An estimated 670,000 total knee arthroplasties (TKAs) were performed annually in the Untied States according to the 2009 Healthcare Cost and Utilization Project(1), with higher

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prevalence in women than men.(2) Total joint arthroplasty (TJA) is associated with decrease in pain, improve functional capabilities and improve quality of life.(3–5) The effectiveness of TKA in achieving these goals has made TKA among the most commonly performed elective surgeries in the elderly.(6) In conjunction with the continued aging of the population, the prevalence of TJA is expected to increase with an estimated 3.5 million TKA's will be performed between 2005 to 2030.(7)

Although TJA is considered to be a relatively safe procedure,(3) only 8.8 percent of men and 12.7 percent of women who are considered candidates for the procedure are willing to undergo surgical intervention.(8) This discrepancy is primarily due to patient uncertainty about the risks associated with surgery.(9) Several known major complications of TJA include venous thromboembolism (VTE) [combination of deep venous thrombosis and pulmonary embolism], myocardial infarction (MI) and even death.(3, 10) Potential predictive factors associated with an increased risk of surgical complications include age, race/ethnicity, medical comorbidities, body mass index, insurance type, hospital procedure volume, and gender.(11–13) (14)

Another important complication of TJA is early implant failure leading to early revision surgery. The surgical revision rate due to implant failure is approximately 1% per year after TKA.(2, 15). Callaghan et al. evaluated 130 studies assessing over nine thousand patients that had undergone primary TKA and reported a surgical revision rate of 4% at a minimum of four-year follow-up.(15) Women comprise almost two-thirds of all patients undergoing TJA in the US.(2) Despite several studies of the effect of gender on pain and functional outcomes after TJA, gender has largely gone under-recognized as it pertains to surgical complications. In recent years, a concern has been raised regarding hip and knee anatomical differences recognized between men and women.(16) Such difference may have implications for surgical outcomes such as revision rates. We used a large regional database, consisting of over 19,000 cases of elective TKAs performed at over 170 hospitals. Our objective was to determine whether, in risk-adjusted analyses, men and women undergoing primary TKA differ in their surgical outcomes and adverse events, as assessed by overall mortality, major complications, hospital readmissions and surgical revision rates..

Materials and Methods

Data Sample and Data Collection

Our study cohort was identified using the Pennsylvania Health Care Cost Containment Council (PHC4) Database, which includes demographic data from all patient discharges from 170 non-governmental (i.e. non–Veterans Administration) acute care hospitals in the State of Pennsylvania. The cohort comprised all cases of primary TKA performed in the state of Pennsylvania during the fiscal year 2002, and outcomes were assessed through fiscal year 2007. Cases were identified using the International Classification of Diseases, Ninth Revision, Clinical Modification Codes 81.54 for primary TKA. Patients who had undergone primary hip or revision knee or hip replacement surgery during the same hospitalization were excluded from the analysis. We excluded patients who had a documented prior TKA, using ICD-9 code v43.65. The dataset includes information on demographics for all patients who underwent TKA or THA. This study cohort and methodology has previously been described in detail.(12)

Study Measures

The primary predictor of interest was gender. Other variables examined as potential confounders of surgical outcome included age, race or ethnicity, hospital teaching status (teaching or non-teaching), insurance status (categorized as none or unknown, Medicaid,

Medicare/ government, or private) and hospital procedure volume. We categorized hospital procedure volume into two levels: 1–100 and greater than 100. This categorization was based on a priori consideration of the potential impact of hospital volume, balanced with consideration of the relatively small number of very-high volume facilities. Based on procedure volume categories in previous work (12), we combined very low (≤25) with low (26–100) procedure volume categories, and we combined high (101–200) with very high (≥200) procedure volume categories.

For surgical mortality risk adjustment, we used the 3M™ All Patient Refined-Diagnosis Related Group Risk of Mortality (APR-ROM)(17) subclass, as assigned in the PHC4 database. This validated risk assessment tool, developed from clinically based models tested with historical data, provides a categorical risk assessment based on patient age, principal diagnosis, the type of surgical procedure, and interactions with co-morbid conditions and combinations of comorbidities. It assigns a risk of death to each patient, for the specific surgical procedure, as minor, moderate, major, or extreme.(18–21). We included the one patient whose APR-ROM category was “Unknown” with the largest risk group, “Minor”, with approximately 80% of men and women, and labeled this group “Minor/Unknown”.

To assess complication rates, we used ICD-9 codes to identify select medical and surgical complications such as: venous thromboembolism (VTE), myocardial infarction (MI), prosthetic device complication and surgical wound infection (Table 1). The overall complication was defined as the occurrence of one or more of the following within 30 days of primary TKA: MI, VTE, prosthesis related complication or surgical wound infection. We identified 30-day readmissions based on the occurrence of any inpatient admission within 30 days of discharge from the index hospitalization. Deaths were identified based on the presence of a non-missing value for the variable indicating the number of days from surgery to death. To assess surgical revision rates, the entire cohort was followed prospectively for up to 5 years after the index surgery (Table 1). The study was approved by the University of Pittsburgh Institutional Review Board.

Statistical Methods

All comparisons of categorical variables between men and women were performed using chi-square tests. Unadjusted comparisons of complication rates between women and men who underwent knee arthroplasty were performed for each individual complication as well as the combined complications. In adjusted analyses, we evaluated gender differences for 30-day complications 30-day readmission, 1-year mortality and surgical revision within 5-years (5-year TKA revision rates). To compare adjusted odds of complications between men and women, we fit mixed effects logistic regression models that accounted for clustering at the hospital level with random hospital intercepts, and included patient age, race/ethnicity, surgical risk of mortality, insurance status and hospital teaching status and procedure volume as fixed effects. We incorporated age as a continuous and categorical predictor, and after confirming that results were essentially identical, we report results based on categorical age. Gender differences in mortality and 30-day readmission were similarly evaluated using mixed effects logistic regression models, controlling for the same covariates. An interaction between gender and surgical risk was tested for inclusion in models for mortality, 30-day readmission, and overall complications. Since this interaction was not significant, we concluded that the effect of gender on these outcomes does not differ across levels of surgical risk.

We estimated unadjusted revision rates using Kaplan Meier survival analysis, in which patients who died or were lost to follow up were censored. To further examine gender differences after adjusting for the covariates listed above, we performed a time to event analysis using competing risks Cox proportional hazards regression. In our analysis we treat

death as a competing risk with respect to surgical revision, rather than as loss to follow up, because death precludes revision, and because it is unlikely that patients who die have the same risk of surgical revision as patients who do not die. We fit a single competing risks proportional hazards model, adjusted for all covariates, and included death as a competing outcome, in addition to surgical revision,. In this way we, estimate the impact of gender on surgical revision, and on death, separately, but within the same model (22). We censored patients who did not experience either revision or death by the end of five years' follow up. . We report hazard ratios for surgical revision estimated from this model. Exploratory analyses revealed that the relationship between gender and surgical revision differed between patients who were under 65 years of age compared to patients aged 65 and over. We incorporated age in models as a continuous and categorical predictor, and after confirming that results were identical, we report hazard ratios adjusted for categorical age noting that the APR-ROM class also incorporates an age adjustment.

We assessed the validity of the proportional hazards assumption for each covariate by testing for correlation between scaled Schoenfeld residuals with the rank of failure time, and by inspecting time-based hazard ratio plots. All statistical analyses were performed using *SAS version 9.2 (SAS Institute, Inc., Cary, NC).*

Results

Baseline Demographic and Clinical Characteristics

We identified 17,994 primary TKA's performed at 170 hospitals in the state of Pennsylvania during the fiscal year 2002 (Figure 1). The median age was 69 years for men and 69 years for women; 84% of the patients were identified as Caucasian while 3% of men and 6% of women were identified as African-American. Race was categorized as either unknown or "Other" for 10% of men and 11% of women. Other demographic and clinical characteristics of the study cohort are shown in Table 2.

Surgical Outcomes, unadjusted comparisons

The surgical outcomes are shown in Table 3. There were no differences in the rates of specific complications such as myocardial infarction, venous thromboembolism, or prosthesis failure by gender. The rates of 30-day wound infection complications were higher in men than women (2.77% and 2.13%, respectively, p=0.007). In terms of overall complications, however, men had higher rates than women of both in-hospital complications (2.04% vs. 1.67%, respectively, p=0.076) and complications within 30 days of the index TKA (6.18% vs. 5.26%, respectively, p=0.010). Men also had higher rates of 30-day readmission (6.74% vs. 5.44%, respectively, p=0.0004) and one-year mortality (1.60% vs. 1.02%, respectively, p=0.0008). In addition, men had higher revision rates, both at one-year (1.76% vs. 1.39%, respectively, p<0.0005) and at five-years (6.23% vs. 5.35%, respectively, p=0.010).

30-day Major Complications from Multivariable Models

In the adjusted multivariable models, there were no statistically significant gender differences with regard to 30-day overall complications, myocardial infarction and venous thromboembolism (Figure 2). There were, however, significantly higher 30-day surgical wound infection rates in men compared to women (OR= 1.31; 95% CI= 1.08–1.60; p=0.007).

30-day Readmission and Mortality from Multivariable Models

After adjusting for age, race/ethnicity, surgical risk, insurance status, hospital teaching status, and hospital procedure volume, the odds of 30-day readmission were significantly higher for men compared to women (OR= 1.25; 95% CI= 1.10–1.43, p=0.0006) following primary TKA (Figure 3). 30-day mortality was rare, with 46 deaths for men and women combined, and we did not fit a multivariable model because this number was too small to support our model with its seven independent variables.

One year Mortality from Multivariable Models

After adjusting for age, race/ethnicity, surgical risk, insurance status, hospital teaching status, and hospital procedure volume, the odds of one-year mortality were significantly higher for men compared to women (OR= 1.48; 95% CI=1.13–1.94, p=0.004) following primary TKA (Figure 3).

Surgical Revision at Five Years from Multivariable Models

After controlling for potential confounding variables in a Cox Proportional hazards model for surgical revision with mortality as a competing risk, allowing hazard ratios to be different for the two outcomes, and incorporating 5-years of follow-up, the adjusted HR for surgical revision, comparing men to women, was 1.20 (95% CI, 1.05–1.36, p=0.006).

Discussion

In this sample of patients from a large regional database, we found that men, compared to women, had significantly higher rates of 30-day surgical wound infection rates compared to women, but we found no significant gender differences with regards to other major complications following TKA. Compared to women, men had higher odds of surgical revision with 5 years follow up after index primary TKA. Clinically, a hazard ratio of 1.20 means that at any given time, 1.20 times as many men as women undergo surgical revision. In addition, the overall mortality one-year after TKA was also higher for men as compared to women. A major advance in our study compared to previous studies of surgical complications is that our analyses account for surgical risk with a measure that includes interactions of multiple comorbid conditions and age with type of surgical procedure, and the principal diagnosis (APR-ROM). This, and our use of competing hazards models to handle mortality and surgical revision, adds methodological and clinical rigor to our study. As a result, we believe that our findings may be less subject to bias due to confounding and modeling limitations, and more generalizable.

Although the literature in this area is sparse, our findings are consistent with that of similar, albeit limited, studies.(15, 23) A previous analysis found that the overall incidence of major surgical complications to be low for both men and women; this supports the general view that TKA is a relatively safe procedure.(24, 25) Previous studies found a higher risk of revision surgery two years after primary TKA(26) and 90-day mortality(27) in men compared to women, and no difference in overall in-hospital complication rate by gender(24), findings consistent with our study. The of revision surgery after TKA in women compared to men was reported in a recent review focused on gender differences.(28) Potential reasons for higher revision rates in men include higher rate of osteolysis (29) and/or higher rates of polyethylene wear and infection,(30) compared to women. One may speculate that the higher rates of wear and osteolysis in men may be related to higher physical activity and/or differences in knee biomechanics. Our finding parallels finding from a previous study found male gender to be associated with higher rate of complications after hip arthroplasty in Medicare population.(31) The higher mortality in men versus women after TKA likely reflects the gender-specific cardiovascular disease mortality advantage for

women, well described in the literature.(32–34) Our study adds significantly to the current knowledge in this area by confirming these findings in risk-adjusted analyses in a large statewide database, and further adds knowledge regarding gender differences by providing complication rates by gender.

Our study addresses a limitation of previous studies that used Medicare database since these studies only included patients greater than 65 years of age. Patients younger than 65 years of age comprise approximately 40% of all total joint arthroplasty recipients.(11) Our study included all patients who underwent TKA in Pennsylvania, and therefore these findings are more generalizable than studies that were limited by focusing only on patients of a limited age range such as in the Medicare dataset. Our findings can be used to inform patients of their risk of complications and revision prior to TKA.

Understanding gender variations in surgical outcomes after total joint arthroplasty is of critical importance since the prevalence of hip and knee OA, as well as the primary indication for elective hip or knee arthroplasty is greater among women than men.(35) Although age-adjusted rates of TJA are higher for women, the overall need for arthroplasty is three times greater for women compared to men.(35) Orthopedic surgeons are more hesitant to recommend joint arthroplasty to women.(36) This may be due to concerns that women may not do as well after surgery compared to men. This concern stems from previous studies that suggested women, compared to men, delay surgery until the OA is more end-stage, which may have an impact on clinical surgical success rates.(37) Interestingly, gender-specific joint prostheses have not been shown to impact peri-operative surgical complications, patient-reported outcomes such as pain and function, or revision rates following primary knee arthroplasty.

There is a growing interest in gender-specific joint prosthesis. Female-specific knees have been marketed to orthopedic surgeons, indicating the possibility of improved surgical outcomes for women despite a paucity of evidence-based peer reviewed studies.(16, 38) Most women do not receive gender-specific implants, which were introduced recently. Therefore, the use of these implants is unlikely to explain the gender-based differences. Although it is possible that gender-specific joint prostheses may impact patient-centered clinical outcomes such as post-procedure pain and function, we were not able to evaluate these outcomes in our database. We did not have sufficient information in our database to assess the possibility that gender-specific joint prostheses provide better surgical outcomes for women compared men in the long-term (i.e., beyond the 5-year post-operative period). Since our study was not designed to assess underlying reason/s for poorer implant survival in men, more research is needed to further investigate the causes of implant failure in men. Our findings should not be over-interpreted to suggest development of male-gender specific implants.

There are important limitations to consider in interpreting the conclusions of this study. First, this analysis used a large administrative database, which was designed for hospital performance assessment, but contains inadequate information on key variables such as body mass index, pre-operative pain, function, and radiographic stage, and post-operative outcomes such patient improvement in pain and function. There may also be potential inconsistencies in documentation. However, the use of administrative databases such as the PHC4 dataset to evaluate patient outcomes has been supported by leading health care quality organizations such as the AHRQ and the Medicare Professional Review Organization.(39) Second, our database lacked information regarding the utilization of specific brand-name of joint prostheses (i.e., the gender-knee). Therefore, with the use of the PHC4 data, we could not accurately compare different types of prostheses nor could we assess patient satisfaction, pain or functional status. It is possible that women may have worse patient-reported

outcomes post-TKA such as less improvement in pain and function, this may impact their decision to undergo revision arthroplasty. Third, our sample consisted of only patients who underwent surgery in the State of Pennsylvania. It is possible that follow-up procedures such as surgical revisions may have been performed out of state for some patients. However, there is no specific reason to assume that state surgical outsourcing should vary by patient gender. Another limitation is that we do not have an accurate capture of previous joint replacements, therefore the revision TKA may be related to the index TKA or contralateral TKA done previously. However, this is the limitation common to all database studies, and not specific to our study only. This misclassification likely biased our results towards null and is not expected to differ by gender, so it is unlikely to explain the observed gender differences. Lastly, our conclusion may not be readily extrapolated to other regions or states of the country, as there is a significant regional variation with regards to the rates of TKAs performed.(40)

In summary, this analysis of nearly 18,000 patients who underwent primary knee arthroplasty in the state of Pennsylvania found that men had more complications, worse outcomes and higher mortality compared to women. Future studies are needed to evaluate whether these findings can be generalized to the nation at large. Our findings showing a higher risk of complications and mortality in men compared to women, adds important knowledge to this field. While women are disadvantaged in care of several health conditions, it is reassuring to see that complications following TKA are in fact lower for women compared to men.

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Significance and Innovation

1. This study provides a risk-adjusted analysis of post-arthroplasty complications from a regional sample of elective primary total knee arthroplasty.
2. Compared to women, men had higher 48% higher adjusted odds of one-year mortality after primary TKA.
3. Compared to women, men had higher adjusted odds of surgical wound infections (31% higher), 30-day readmission (25% higher) and 5-year revision hazard rate at (20% higher), findings that add to the current knowledge.

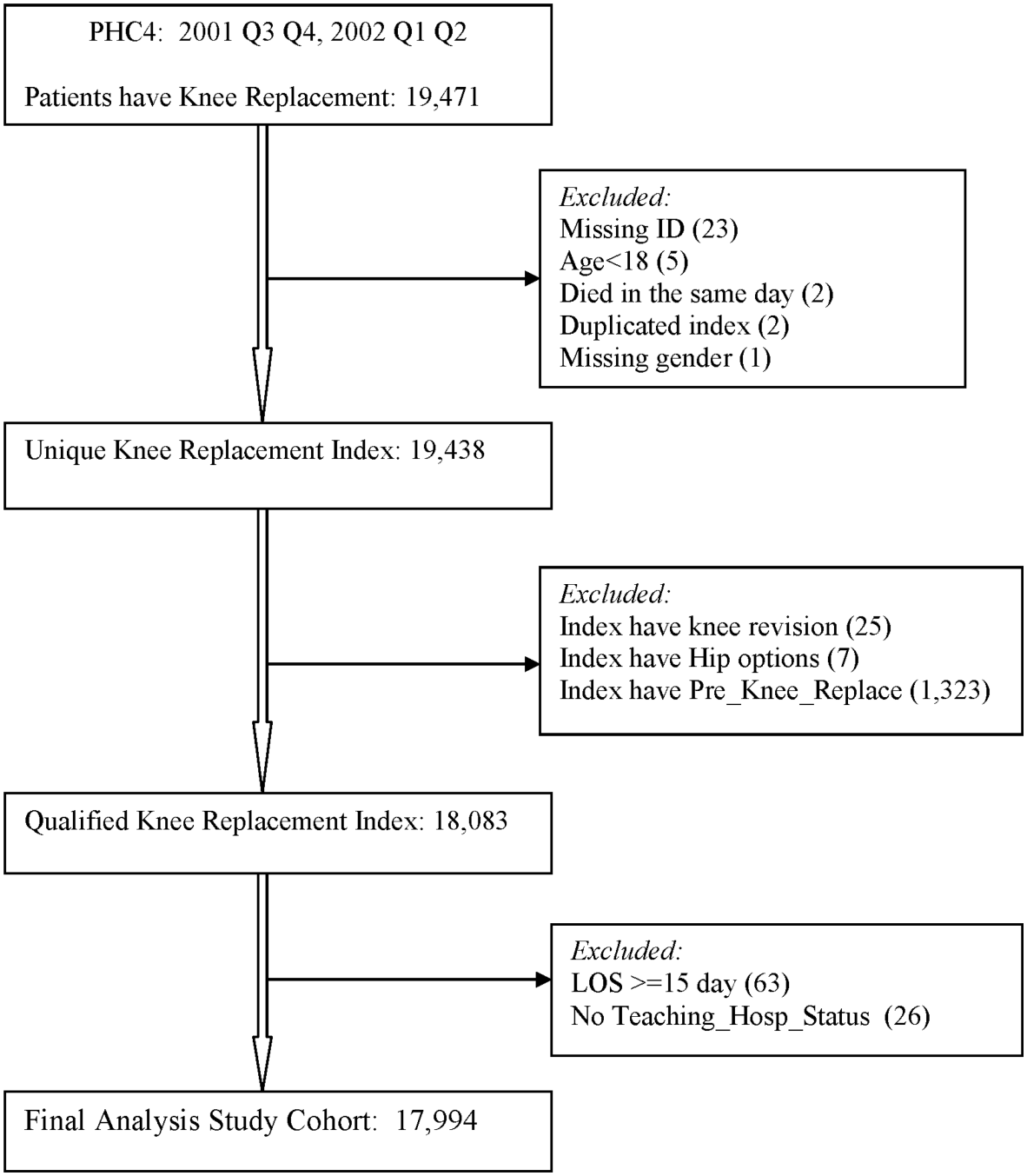

Figure 1.
Patient Selection Flow Chart

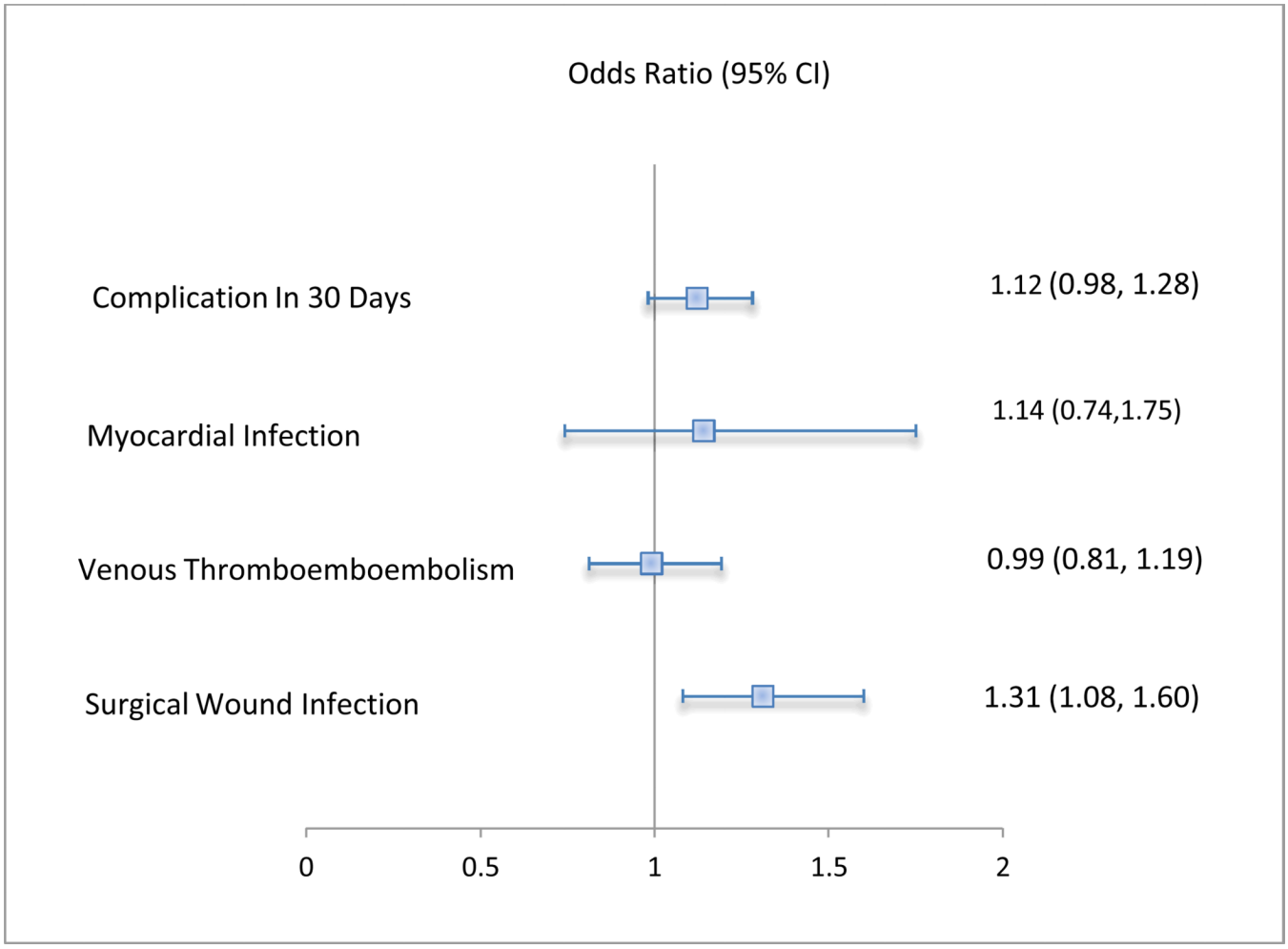

Figure 2.

Adjusted Odds Ratios for Complications within 30 days in Males post primary total knee arthroplasty (TKA), with Females as reference category

Analyses were adjusted for age category, race, surgical risk category, insurance group, teaching status and hospital procedure volume

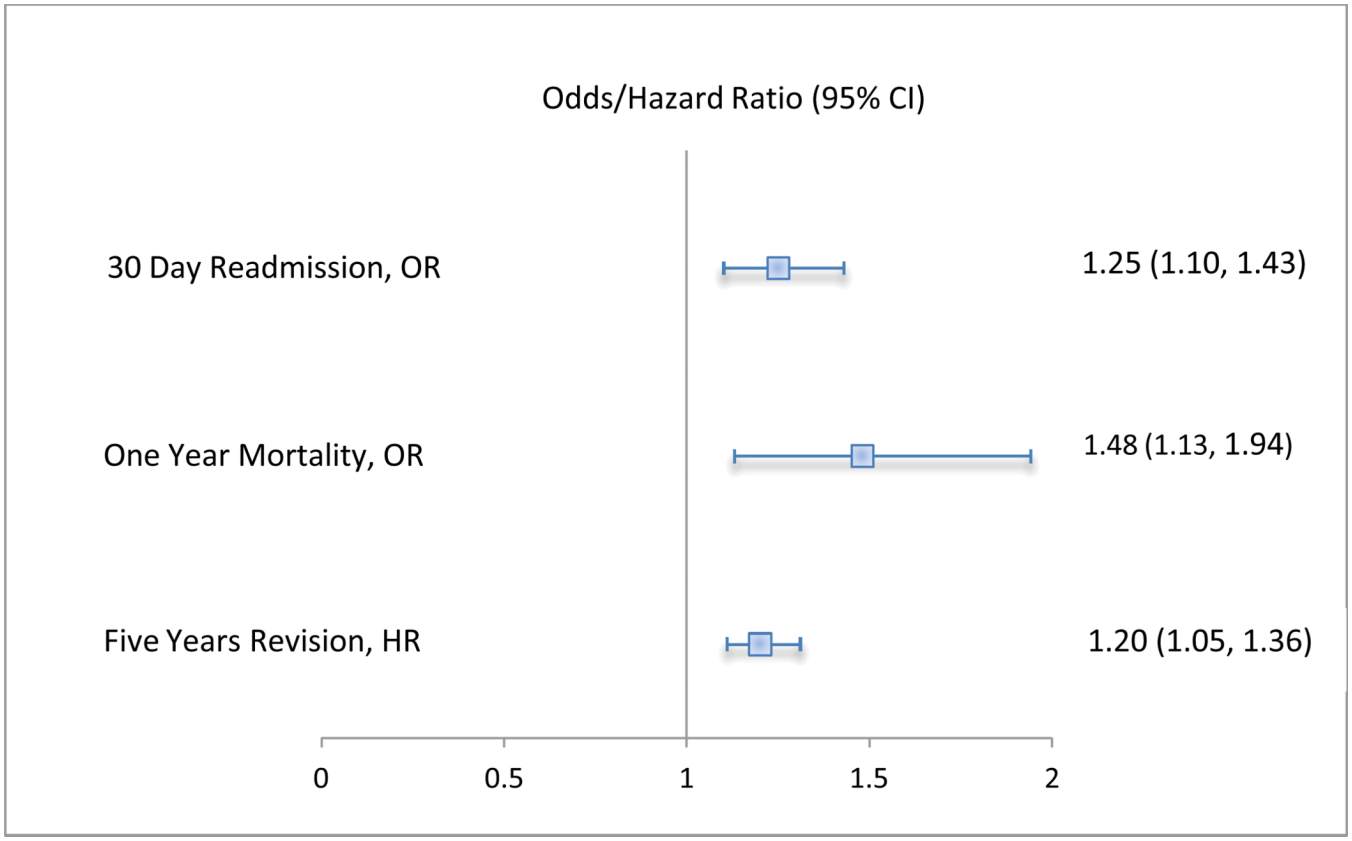

Figure 3.

Adjusted Odds Ratio (OR) for 30-day Readmission and 1-year Mortality and adjusted Hazard ratio (HR) for 5-year revision rate in Males after knee arthroplasty, with Females as reference category

Analyses were adjusted for age category, race, surgical risk category, insurance group, teaching status and hospital procedure volume

Table 1

Diagnostic codes for complications

Complications	ICD-9 codes
Venous thromboembolism (VTE)	415.1, 415.11, 415.19, 451.11, 451.19, 451.2, 451.81, 451.9, 453.40, 453.41, 453.42, 453.8, 453.9
Myocardial infarction (MI)	410.00, 410.01, 410.10, 410.11, 410.20, 410.21, 410.30, 410.31, 410.40, 410.41, 410.50, 410.51, 410.60, 410.61, 410.70, 410.71, 410.80, 410.81, 410.90, 410.91; additional code of 997 with any of the above for post-operative MI
Prosthetic device complication	996.40, 996.41, 996.42, 996.43, 996.46, 996.47, 996.49
Surgical wound infection	682.5, 682.6, 682.8, 682.9, 998.51 and 998.59
Revision TKA Surgery	81.55, 0080, 0081, 0082, 0083, and 0084

Table 2

Clinical and demographic characteristics of patients who underwent primary total knee arthroplasty (TKA) (n=17,994)

	Female (n=11,669)	Male (n=6,325)	P-value
Race (%)			**<0.0001**
White	84.2	86.2	
African American	5.9	3.3	
Unknown/other	10.0	10.6	
Hospital teaching status (%)			0.9386
Teaching hospital	24.6	24.7	
Non-teaching hospital	75.4	75.3	
Surgical Risk of Death (%)			**<0.0001**
Minor/Unknown	81.4	77.9	
Moderate	15.1	17.4	
Major/Extremely Likely	3.5	4.7	
Insurance (%)			**<0.0001**
Missing/No/Unknown	0.4	0.3	
Government	62.0	59.4	
Medicaid	3.3	1.7	
Private	34.5	38.7	
Hospital procedure volume (median (IQR))	172 (111–279)	182 (112–290)	**0.0028**
Hospital procedure volume (%)			0.2053
1–100	24.4	23.5	
>100	75.6	76.5	
Age (median (IQR))	69 (60–76)	69 (60–75)	0.0876
Age (%)			0.6468
18–64 years	36.6	36.2	
≥65 years	63.5	63.8	

Note:

* P-values are based on chi-square tests for categorical variables, and the Wilcoxon rank-sum test for numeric variables (age and volume); Significant p-values are in **bold.**

Table 3

Surgical outcomes of primary total knee arthroplasty (TKA) presented as n (%)

	Total (n=17,994)	Female (n=11,669)	Male (n=6,325)	P-value
In-Hospital Complications				
Overall complications	324(1.80%)	195 (1.67%)	129 (2.04%)	**0.076**
Myocardial Infarction	60 (0.33%)	35 (0.30%)	25 (0.40%)	0.28
Venous thromboembolism	184(1.02%)	119 (1.02%)	65 (1.03%)	0.96
Surgical wound infection	60 (0.33%)	29 (0.25%)	31 (0.49%)	**0.007**
Prosthesis failure or device complication	30 (0.17%)	16 (0.14%)	14 (0.22%)	0.186
30-day Complications				
Overall complications	1005 (5.59%)	614 (5.26%)	391(6.18%)	**0.010**
Myocardial Infarction (MI)	89 (0.49%)	50 (0.43%)	39 (0.62%)	0.086
Venous thromboembolism (VTE)	482 (2.68%)	305 (2.61%)	177 (2.80%)	0.46
Surgical wound infection	423 (2.35%)	248 (2.13%)	175 (2.77%)	**0.007**
Prosthesis failure or device complication	55 (0.31%)	33 (0.28%)	22 (0.35%)	0.451
Readmission and Mortality				
30-day readmission	1061 (5.90%)	635 (5.44%)	426 (6.74%)	**0.0004**
30-day mortality[1]	46 (0.26%)	24 (0.21%)	22 (0.35%)	0.071
1 year mortality[1]	220 (1.22%)	119 (1.02%)	101 (1.60%)	**0.0008**
Revision Rates[2]				
1 year revision	298 (1.57%)	162 (1.39%)	136 (1.76%)	**<0.0005**
5 year revision	1012 (5.66%)	627 (5.35%)	385 (6.23%)	**0.01**

[1] Mortality (#patients who died/ total #patients);

[2] Revision rates estimated using the Kaplan-Meier method; p-values are based on the log-rank test